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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/886,954	06/21/2001	Maureen J. Charron	96700/667	6743

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EXAMINER	
KAUSHAL, SUMESH	
ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 10/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/886,954	Applicant(s) CHARRON ET AL.	
	Examiner S. Kaushal	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-35* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-35 were pending and were examined in this office action.

If the claims are amended, added and/or canceled in response to this office action the applicants are required to follow Amendment Practice under 37 CFR § 1.121 (http://www.uspto.gov) and A CLEAN COPY OF ALL PENDING CLAIMS IS REQUESTED

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, **8-10**, 11-13, **18-20** and 21-23 are drawn to a method of diagnosis, assessing the efficacy of therapy and prognosis of a subject who has defect in cell proliferation by assaying GLUTx expression using an a nucleic acid probe, classified in class 435, subclass 6.

II. Claims 1-3, **4-7**, 11-13, **14-17** and 21-23 are drawn to a method of diagnosis, assessing the efficacy of therapy and prognosis of a subject who has defect in cell proliferation by assaying GLUTx expression using a antibody, classified in class 435, subclass 7.1.

III. Claims 24-28, drawn to a method of treating a defect in cell proliferation in a subject using a compound that inhibits GLUTx, classified in class 514, subclass 1.

IV. Claims 24-27 and 29, drawn to a method of treating a defect in cell proliferation in a subject using an oligonucleotide antisense to GLUTx, classified in class 514, subclass 44.

V. Claims 30-31 and 34 are drawn to method of treating ischemia in a subject by administering GLUTx protein, classified in class 514, subclass 2.

VI. Claims 32-34 are drawn to method of treating ischemia in a subject by administering nucleic acid encoding GLUTx, classified in class 514, subclass 44. ***Note:*** *Claim 32 does not further limit claim 30, since claim 30 requires the administration of GLUTx protein whereas claim 32 requires the administration of nucleic acid sequence encoding the GLUTx protein .*

VII. Claim 35 is drawn to method of treating ischemia in a subject by administering a GLUTx modulator, classified in class 514, subclass 1.

The inventions are distinct, each from the other because of the following reasons:

Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In instant case, the inventions of methods of diagnostic (Group I, II) are distinct from method of treatment (Group III, IV, V VI, VII), since these have different modes of operation, different functions, or different effects. For example, the method of diagnostic requires the detection of a protein using an antibody in vitro whereas the treatment requires the administration of therapeutic agents in vivo. Furthermore, the method of treating a defect in cell proliferation (Groups III, IV) are distinct from the method of treating ischemia (Groups V, VI, VII), since these have different modes of operation, different functions, or different effects. For example, the treatment of a cancer (defect in cell proliferation) requires the killing of cancer cells whereas the treatment of ischemia requires the regeneration of damaged heart tissue. Thus these inventions are distinct and are of separate uses.

Inventions I and II are distinct. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case groups I and

II are distinct because detection of gene expression by using nucleic acid probes is distinct from the detection of a protein using an antibody. Furthermore, each method requires the use of materially different products. Thus these inventions are distinct and are of separate uses.

Inventions III and IV are distinct Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In instant case, inventions of groups III and IV require the use of a compound and antisense oligonucleotides respectively to alter cellular proliferation, which have different modes of operation, different functions, or different effects. For example compound could be a synthetic chemical molecule, which interacts with any factor involved in the synthesis of GLUTx protein, whereas an antisense molecule would specifically block the transcription of the GLUTx protein. Thus these inventions are distinct and are of separate uses.

Inventions V, VI and VII are distinct. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In instant case inventions of groups V, VI and VII are distinct, since the protein therapy is distinct from gene therapy, which have different modes of operation, different functions, or different effects. For example, proteins are biological active compounds whereas nucleic acid requires to be administered via a genetic vector. Proteins are active compounds whereas therapeutic gene must be efficiently expressed to cause therapeutic effect. In addition the mode of action of a GLUTx modulator is distinct from the method of gene and protein therapy. Thus these inventions are distinct and are of separate uses.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Claims 1-3 link(s) inventions I and II. The restriction requirement between the linked inventions is subject to the non-allowance of the linking claim(s), claims 1-3. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 24-27 link(s) inventions IV and V. The restriction requirement between the linked inventions is subject to the non-allowance of the linking claim(s), claims 24-27. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is (703) 305-6838. The examiner can normally be reached on Monday-Friday from 9:00 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Irem Yucel Ph.D. can be reached on (703) 305-1998. The fax-phone number for the organization where this application or proceeding is assigned as (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst Zeta Adams, whose telephone number is (703) 305-3291.

S. Kaushal
PATENT EXAMINER

Scott D. Priebe

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER